



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 11 1977

OFFICE OF ENFORCEMENT

SUBJECT: Enforcement Policy Applicable to Bulk Shipments of Pesticides

TO: Regional Enforcement Division Directors
Pesticide Branch Chiefs

I. Purpose

It has come to our attention that an increasing practice among manufacturers and distributors of pesticides involves the transport and transfer of pesticides in large quantities, i.e., "bulk". 1/ Among the reasons that manufacturers and distributors prefer to handle pesticides in bulk rather than in small individual containers are the following: 1) the need to properly dispose of excess numbers of containers is eliminated; 2) less warehouse space is required; 3) labor and handling costs are reduced; and 4) inventories can be more accurately controlled.

In the interest of energy and resource conservation and of improved safety measures in pesticide handling, it is incumbent upon the Agency to encourage and endorse these practices in so far as they are consistent with the broad purposes of FIFRA. Because the practices involved in "bulk" shipment and transfer are in some cases unclear in or are unaddressed by the Act and regulations, the development of an enforcement policy to define the limits of the "bulk" shipment and transfer practice is needed.

1/ For purposes of this policy, the term "bulk" refers to any volume of pesticide greater than 55 gallons or 100 pounds held in an individual container. Examples of bulk quantities of pesticides are: creosote in barges, weed oil in tank cars, liquid herbicide in tank trucks or rail cars, or any of these in standing storage tanks.

II. Policy and Rationale

A. Policy Summary

For purposes of enforcement of the Act, it is the policy of the Agency that so long as the transfer of a registered pesticide in "bulk" involves only the changing of the product container with no change 1) to the pesticide formulation, 2) to the product's accepted labeling (with exceptions noted in Part III B and C below, and 3) to the identity of the party accountable for the product's integrity, the new product resulting from transfer will be considered as encompassed within the terms of the registration of the product which was transferred. This rationale applies to the transfer of supplementally registered products, as well as to the basic registered product.

B. Rationale

The basis for this policy is published in the Appendix to PEPS No. 6 (41 Fed. Reg. 55932) as follows:

FIFRA section 3(a) [7 U.S.C. 136a(a)] provides in pertinent part that

* * * no person * * * may distribute, sell, offer for sale, hold for sale, * * * to any person any pesticide which is not registered with the Administrator.

Before a pesticide product which is not encompassed within the terms of an existing registration enters the channels of trade, a separate registration must be obtained. Changes in the formulation of a registered product, changes in accepted labeling, as well as any repackaging of a pesticide into another container will activate the registration requirement, unless the purposes of product registration would be fully met by carrying forward the Federal registration of the constituent product.

The broad purposes of the registration process are four fold. First registration of a product provides a mechanism for the review of information regarding the safety and efficacy of the pesticide as proposed for use (and as likely to be used) under widespread and commonly recognized practice. Second, registration of a product provides EPA with the opportunity to review the proposed label and labeling of the product. To support registration, such labeling must clearly communicate the directions for use for the

product and such warnings and precautions as are necessary for the safe and efficacious use of the pesticide. Third, registration of a product identifies the party accountable for its integrity of composition, labeling and effects resulting from use. Fourth, registration of a product is the mechanism which assures that this relevant information is communicated to the ultimate user of the product.

III. Elaboration of Policy Relating to Specific FIFRA Requirements

A. Section 3

The commercial transfer of a pesticide in "bulk" may, at various stages of the shipping or distribution process, involve changing the container of the pesticide. Because "changing the container" or "repackaging" amounts to production within the meaning of 40 CFR 167.1(c), and because the resulting product is a pesticide and is being held for sale and distribution within the channels of trade, it is subject to the registration requirements of section 3. The key to determining the applicability of section 3 to a repackaged bulk product is whether the purposes of registration continue to be satisfied upon further sale and distribution after transfer. These purposes outlined above include: safety and efficacy review, label review, identification of the accountable party, and communication to the user of relevant information. Thus, to the extent that a bulk transfer involves changing the container, e.g., repackaging a registered end-use pesticide with no change to the pesticide formulation, its labeling, or the accountable party, the repackaged product is encompassed within the terms of the original registration. This means that the original registration will have satisfied the purposes of section 3 as to the repackaged pesticide. Conversely, if any of these factors change, the corresponding purpose of registration will be unsatisfied, thereby activating the registration requirement for the repackaged product.

In the context of the bulk transfer practice the most difficult of these criteria to satisfy is accountability. For purposes of this policy, the accountability requirement will be considered as met when a pesticide 1) is transferred in bulk at an establishment owned by the registrant as specified in 40 CFR 162.3(dd)(1), 2/ 2) is transferred

2/ 40 CFR 162.3(dd) provides:

(dd) The term "operated by the same producer" means (1) another registered establishment owned by the registrant of the pesticide product or (2) another registered establishment operated under contract with the registrant of the pesticide either to package the pesticide product or to use the pesticide as a constituent part of another pesticide product provided that the final pesticide product is registered by the transferor establishment.

at a registered establishment operated under contract with the registrant within the meaning of 40 CFR 162.3(dd)(2), or 3) is transferred at a registered establishment owned by a party not under contract to the product registrant, but who has been furnished written authorization for use of the product label by the registrant. The written authorization may apply to a supplemental registrant's label as well as to a basic product label. If a supplemental registrant's label is involved, the written authorization must still be supplied to all transfer points by the basic registrant. The supplemental registrant cannot satisfy the written authorization requirement.

This provision for satisfying accountability may be utilized at as many points down the chain of distribution as the product registrant cares to authorize. However, at any point where a pesticide is transferred and repackaged in bulk by a person other than the registrant, his agent as provided in 40 CFR 162.3(dd)(2) or one authorized by the registrant under written agreement with the registrant to transfer the product and to retain use of the registrant's label, the requirement of accountability has not been met. The resulting transferred and repackaged pesticide is considered a different pesticide no longer encompassed within the terms of the original registration and is subject to separate registration under section 3.

Sale and distribution of a pesticide transferred and held for sale under conditions other than the three outlined above and therefore in a manner which fails to satisfy the conditions of registration, will subject the party responsible for such transfer, and for subsequent sale and distribution, to the sanctions of section 12(a)(1)(A) of the Act for sale and distribution of an unregistered pesticide. Failure to supply the required label, with each sale will subject the seller to enforcement liability under section 12(a)(1)(E) for sale and distribution of a misbranded pesticide.

B. Section 2(g)

Section 2(g) lists various types of information which must appear on each pesticide label. In those cases (outlined in Part A above) where the conditions of transferal repackaging do not activate the section 3 registration requirement, the original registered label will be attached to the transferred product; 3/ however, this label must reflect the establishment number of the establishment at which

3/ Label placement must conform to the requirements of 40 CFR 162.10 (a)(4)(ii)(A) and (B)

the product was transferred (unless otherwise specified in part C below) and the appropriate net content statement. Failure to include accurate establishment registration and net content information on the label subjects the transferor to enforcement liability under section 12(a)(1)(E).

C. Section 7

Regulations pursuant to section 7 (40 CFR Part 167) provide that the act of repackaging constitutes production and thereby activates the need for establishment registration. All establishments, therefore, in which bulk pesticides are transferred or repackaged are subject to section 7.

The Agency has determined, however, that the purposes of the Act are not substantially furthered by enforcing the establishment registration requirement for repackaging or transfer establishments when such repackaging or transfer is performed by an establishment owned by the same person who previously produced the product within the meaning of 40 CFR 162.3(dd)(1). Thus, for purposes of this policy, establishments owned by the registrant which engage only in transfer and repackaging in bulk need not be registered pursuant to section 7 and products transferred and repackaged in such establishments may retain the label showing the number of the establishment in which the original product subject to transfer and repackaging was produced.

However, when the repackaging or transfer is performed in an establishment owned by a person other than the registrant e.g., by a person operating under contract to the registrant pursuant to 40 CFR 162.3 (dd)(2) or by a person authorized by the registrant to use his label on the transferred and repackaged pesticide, that establishment must be registered and the product label must show that establishment number. This label modification may be accomplished by stickering. Failure to register producing transferring establishments as defined at 40 CFR 167 (other than those specifically exempted in this policy statement) and to reflect the establishment number on transferred products, may subject repackagers to the sanctions of section 12(a)(2)(L) of the Act for violation of section 7 and section 12(a)(1)(E) for sale and distribution of a misbranded product.

IV. Examples

A. A registrant ships a bulk pesticide to a new owner (dealer/distributor). The dealer holds the pesticide in labeled storage tanks until the material is sold in bulk quantities to end-use applicators, with the original label accompanying. The dealer's establishment number is on the label or container. The basic registrant has furnished the new owner (dealer) written authorization for use of the registrant's label. The purposes of Section 3 registration are satisfied.

B. A registrant ships a bulk pesticide directly to an end user (custom applicator, farmer, etc.). The label accompanies the shipment and is placed on the user's tank. No new establishment or product registration is needed for the bulk container since the labeled product is fully registered and has been sold intact to the user.

C. A registrant ships a bulk pesticide to a new owner (dealer/distributor). The registrant furnishes the dealer written authorization for use of the registrant's label only to accompany material from the dealer's tanks to end-use applicators. If the dealer sells from his tanks to a second dealer for subsequent sale to an end user, the purposes of registration are not served by the sale to the second dealer. The accountability requirement will not be considered met by virtue of non-authorization of the registrant's label for such an action. The product will be considered not registered and the dealers will be subject to enforcement sanctions under sections 12(a)(1)(A) and 12(a)(1)(E) for selling and distributing unregistered and misbranded pesticides.

Responsibility for movement of a product from the registrant to Dealer A to Dealer B and to the user is considered analogous to a registrant that sells a sealed 55-gallon drum of a pesticide to a dealer who sells the drum to another dealer. If the drum was then decanted into 11/5-gallon cans, the registrant could not be held accountable for his product, nor would the decanted product be considered registered.

D. A registrant may wish to have a dealer "operate under contract" for him as a producer. 40 CFR 162.3(dd) allows the registrant to enter formal contractual agreements that, in effect, make the contract producer an extension of the registrant's own production facilities, and both share enforcement liability for the product integrity. Under this arrangement, the registrant's label would be placed on the bulk pesticide produced and released for shipment by the contract producer (dealer) establishment. Any further transfer of the pesticide in bulk quantities would be subject to the provisions of this policy.

E. A registrant ships a bulk pesticide to a new owner (dealer/distributor) and refuses to furnish written authorization to use his label. If the dealer sells the pesticide, he will be considered to have sold an unregistered pesticide in violation of Section 12(a)(1)(A) and a misbranded pesticide in violation of Section 12(a)(1)(E). Without such written authorization for the use of the registrant's label, there is no identification of the party accountable for its integrity of composition, labeling, and effects resulting from use.

F. A tank car of pesticide from which commercial applicators meter off into their own tanks, without being put into a dealer's holding tank, would be exempt from new producer establishment registration. It is considered that the original container has not been changed in delivery to the applicator and the tank car label (placard) will bear the producer's establishment number. The commercial applicator would be bound by the general labeling requirements of PEPS VI if the pesticide is transported or stored. The application of PEPS VI to agricultural pest control operators will be elaborated in the enforcement policy for custom blenders and custom applicators.

A handwritten signature in dark ink, appearing to read "A E Conroy II". The signature is fluid and cursive, with the first and last names being more prominent than the middle initial.

A. E. Conroy II, Director
Pesticides and Toxic Substances
Enforcement Division

MAR 4 1991

Amendment to the July 11, 1977 Enforcement Policy
Applicable to Bulk Shipment of Pesticides

The July 11, 1977, Bulk Policy is hereby amended to allow repackaging of any quantity of pesticides into refillable containers, provided:

1) the container is designed and constructed to accommodate the return and refill of greater than 55 gallons liquid or 100 pounds of dry material; and

2) either: (a) the containers are dedicated to and refilled with one specific active ingredient in a compatible formulation, or (b) the container is thoroughly cleaned according to written instructions provided by the registrant to the dealer prior to introducing another chemical to the container in order to avoid cross-contamination; and

3) all other conditions of the July 11, 1977 policy are met.

This amendment does not preclude States or territories from developing more stringent restrictions to this policy or from disallowing the application of this amendment/policy and taking appropriate state enforcement action for violations.

Repackaging in accordance with this policy does not exempt the repackager from the Child Resistant Packaging Rule, 40 CFR 157, Subpart B, if applicable.

Footnote 1 on page 1 of the July 11, 1977 policy is amended by the deletion of the first sentence.

Rationale

EPA is amending the July 11, 1977, policy to address the changes that have taken place in the distribution of pesticide formulations that could be applied in greatly reduced quantities. The Agency is concerned with the difficulties of container disposal which is becoming a growing problem in many areas. By placing no lower limit on the quantity of pesticide that may be introduced into refillable bulk containers, the Agency will significantly reduce the number of containers requiring disposal and will minimize leftover pesticide product that results from sales in predetermined quantities.

All other provisions of the policy remain in effect as a means of safeguarding product integrity and accountability of the parties involved. The Agency remains concerned with the issue of cross contamination and is thus requiring that the bulk

containers either be dedicated to a particular active ingredient which is compatible to other formulations with the same active ingredient, or that registrants involved in the bulk shipment and transfer of pesticides provide the dealer with written instructions to follow for cleaning the container prior to introducing another pesticide into the container.